REMARKS

Claims 1-66 are pending. Claims 28-66 have been withdrawn as being directed to a non-elected invention. Applicant reserves the right to pursue these claims in a later filed application claim priority to the subject application. Applicant has reviewed the Office Action mailed March 14, 2006, and respectfully traverses all grounds of rejection for the reasons that follow.

Rejections Under 35 U.S.C. § 102

Claims 1, 4-6 and 8-11 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gorsek, U.S. Patent No. 6,103,756. The Office alleges that Gorsek describes a formulation containing vitamins C, E, and A; selenium, and four high potency antioxidants corresponding to alpha lipoic acid, quercetin, rutin and citrus bioflavoniods.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Examiner must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

The invention claims a nutrient composition for augmenting immune strength or physiological detoxification. The nutrient composition includes an optimal combination of an effective amount of at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants. The claimed invention is distinct from Gorsek because Gorsek does not describe a nutrient composition containing four high potency antioxidants.

The Office cites to column 1, lines 56-65 and claim 3 of Gorsek, alleging alpha lipoic acid, quercetin, rutin and citrus bioflavoniods to correspond to four high potency antioxidants. However, application excludes at least three of the alleged high potency antioxidants pointed to in Gorsek in its definition of this term as follows:

> [T]he term "high potency" when used in reference to an antioxidant is intended to mean a non-vitamin or non-mineral antioxidant. . . . Specific examples of high potency antioxidants include alpha lipoic acid, acetyl L-carnitine, N-acetyl cysteine, coenzyme Q10 and glutathione.

Application at paragraph [025] (emphasis added).

A high potency antioxidant as it is described and claimed by the invention excludes vitamin and mineral antioxidants. Notably, the exemplified high potency antioxidants do not include three of the alleged high potency antioxidants pointed to in Gorsek. Applicants respectfully point out that rutin, quercetin and citrus bioflavonoids are vitamin antioxidants and, therefore, do not constitute a high potency antioxidant of the invention.

The application specifically teaches that rutin, quercetin and citrus bioflavonoids (ie, citrin) are vitamin antioxidants when it describes:

> Bioflavinoid complex, or vitamin P, includes the substances rutin, citrin, hesperidin, and quercitin.

Application at paragraph [042] (emphasis added).

Therefore, Gorsek fails to describe a composition containing at least three high potency antioxidants as claimed by the invention because the antioxidants rutin, quercetin and citrus bioflavonoids constitute vitamins, not non-vitamin or non-mineral antioxidants. Absent a showing that Gorsek describes all elements of the claimed invention, Gorsek cannot anticipate the invention as claimed and withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1-27 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kosbab, U.S. Patent Application 2001/0031744. The Office alleges that Kosbab describes an exemplary formulation dosage containing at least one vitamin antioxidant, at least one mineral antioxidant and at least three high potency antioxidants and alleges that weight ranges for exemplary formula components encompass those disclosed in the application. The Office concedes that Kosbab does not expressly disclose a nutrient composition having highly saturable amounts of at least three high potency antioxidant, but concludes that one skilled in the art would have been motivated to modify the composition of Kosbab to arrive at the claimed invention allegedly

because Kosbab provides the preferred dosage ranges of formula components such that one skilled in the art could reduce to practice the instant invention by adding highly saturable amounts of at least 3 high potency antioxidants.

To establish a *prima facie* case of obviousness, the Office must show that the prior art would have suggested the claimed invention to one of ordinary skill in the art and that it could have been carried out with a reasonable likelihood of success when viewed in the light of the prior art. *Brown & Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000), accord *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974) (to establish *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art); M.P.E.P. §2143.03.

The invention claims a nutrient composition for augmenting immune strength or physiological detoxification. The nutrient composition includes an optimal combination of an effective amount of at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants. The claimed invention is unobvious over Kosbab because Kosbab fails to suggest a formulation containing highly saturable amounts of at least three high potency antioxidants.

The Office's conclusionary statement that "Kosbab provides the preferred dosage ranges of formula components such that one of ordinary skilled in the art could reduce to practice the instant invention by . . . adding highly saturable amounts of at least 3 high potency antioxidants" (Office Action mailed March 14, 2006, p.6, last para.) fails to show or articulate why one of ordinary skill would be motivated to include (1) at least three high potency antioxidants and (2) include them in highly saturable amounts. In particular, the Office relies on Table 4 for showing a formulation allegedly containing three high potency antioxidants. However, alpha lipoic acid, N-acetyl-cysteine and acetyl L-carnitine are listed in Table 4 in concentrations lower than that claimed by the invention. As set forth in the subject application, a highly saturable amount of the claimed high potency antioxidants refers to:

> [A]n amount of high potency antioxidant that maintains an excess of reduction potential during the course of treatment. Highly saturable amounts are in excess of the RDA, preferably in about 10-fold excess of the RDA and more preferably in about 20-fold excess of the RDA.

Application at page 9, para. 27.

In contrast, Kosbab lists as "Exemplary Diabetic Compilations Formulation Dosages" alpha lipoic acid to be included at 20 mg; N-acetyl-cysteine to be included at 200 mg, and acetyl L-carnitine to be included at 50 mg. These formulation dosages are less than the amount of high potency antioxidants as described and claimed by the invention.

The Office further relies on dosages listed in Table 3 purported to list preferred dosage ranges for components of exemplary formulations. Applicants respectfully point out that Table 3 of Kosbab merely provides a listing of all components having very general ranges. The lack of specificity for the component ranges in Table 3 of Kosbab fails to teach, suggest or provide the requisite motivation to combine three high potency antioxidants in highly saturable amounts in a single composition. Absent such a teaching suggestion or motivation to arrive at the claimed combination of three high potency antioxidants all in highly saturable amounts, the Office has not met its burden.

Further, the law is clear with respect to the requirements for properly combining elements. Simply identifying elements in the cited art fails to render a claimed invention obvious absent a specific reason to do so. Here, Table 3 lacks sufficient, if any, specificity such that one of ordinary skill would be able to "reduce to practice the instant invention by . . . adding highly saturable amounts of at least 3 high potency antioxidants" (Office Action at p.6, last para.) because there is no teaching or suggestion as to what amount, within the general range of listed amounts, constitutes a highly saturable amount. Similarly, because Table 4 also fails to teach or suggest what constitutes a highly saturable amount of a high potency antioxidant, there can be no specific reason to combine any dosage listed in Table 3 with the formulation in Table 4 to arrive at a third, and different, composition containing at least three high potency antioxidants in highly saturable amounts.

Recent authority has particularly pointed out the required analysis for establishing motivation to combine when the claimed combination of elements are alleged to be found from different teachings. The "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *In re Kahn*, Case No. 04-1616, slip op. at p.11 (Fed. Cir. March 22, 2006) (citing *In re Rouffet*, 149 F.3d 1350, 1355, 1357

(Fed. Cir. 1998)). Further, *In re Kahn* emphasized that to guard against hindsight, the motivation of one of ordinary skill in the art to combine must be explained. *Id.*, slip op. at pp.11-12.

As articulated by the Office, the mere listing of dosages fails to provide the proper motivation to combine a highly saturable amount with at least three high potency antioxidants because it does nothing more than identify one element of the claim. Similarly, the mere listing of a formulation containing antioxidants less than in a highly saturable amount also fails to provide the proper motivation to combine because it too does nothing more than identify one element of the claimed invention. Neither description provides any teaching or suggestion as what constitutes a highly saturable amount or as to why three high potency antioxidants should be included in highly saturable amounts. Other than the generalized conclusion by the Office that one of ordinary skill "could reduce to practice the instant invention by . . . adding highly saturable amounts of at least 3 high potency antioxidants," (Office Action at p.6, last para.) no explanation has been provided in either Kosbab or in the Office Action that would provide a basis for combining (1) at least three, (2) high potency antioxidants, and (3) all in highly saturable amounts. Therefore, Kosbab cannot provide a motivation to combine the separate descriptions to arrive at the claimed invention and the Office's rejection constitutes improper hindsight.

In re Kahn explained further that in the motivation analysis, the problem examined is "the general problem that confronted the inventor before the invention was made." *In re Kahn*, Case No. 04-1616, slip op. at 15 (*citing Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323 (Fed. Cir. 2005)). "Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1372 (Fed. Cir. 2000) (internal citation omitted) (*quoting Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998).

One problem facing the inventor solved by the claimed invention is directed to providing an optimal combination of vitamin, mineral and high potency antioxidants that enhance immune strength (see, for example, para. [017] and claim 1). There is nothing in Kosbab which provides the motivation to arrive at the claimed invention as a solution to this problem facing the inventor

- namely, an optimal combination of an effective amount of at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants.

Kosbab describes five different base formulas (I-V) and additions thereto which are purported to be used for the prevention and treatment of chronic diseases and disorders including the complications of diabetes mellitus. However, neither the base formulas nor the additional components teach or suggest the claimed nutrient composition containing at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants. Rather, Kosbab establishes a formulation pattern of beginning with a base Formula having components appearing to be unrelated to the claimed nutrient composition and then adds constituents which also appear to be unrelated to the claimed composition. This pattern continues throughout the listing of all five of the base Formulas I-V described by Kosbab.

For example, Formula 1A includes plant extracts (bilberry extract), tea polyphenols, zinc and soy isolate. Kosbab at para. [0020]. Three of these four components are not described as, and are unrelated to, the components of the claimed nutrient composition.

Formula 1B includes, in addition to vitamins B, E, and zinc, the compounds bilberry extract, pine bark extract, tea polyphenols, and soy isolate. *Id.* at para. [0025]. These additional ingredients also are not described as, and are unrelated to, the components of the claimed nutrient composition.

Formula 1C includes Formula 1B plus glucosamine sulfate (*Id.* at para. [0035]), which is a glycosaminoglycan used for collagen synthesis that is again not described as, and is unrelated to, the components of the claimed nutrient composition.

Formula 1D includes Formula 1C plus lutein and/or zeaxanthin (*Id.* at para. [0038]), which are carotenoids that are not described as, and are unrelated to, the components of the claimed nutrient composition.

Formula 1E includes Formula 1D plus grape seed extract, taurine, a non-antioxidant amino acid, plus a variety of minerals. *Id.* at para. [0042]. Grape seed extract and taurine are not described as, and are unrelated to, the antioxidants of the claimed nutrient composition.

Formula 1F includes Formula 1E plus essential fatty acids and several B vitamins. *Id.* at para. [0051]. Fatty acids are not described as, and are unrelated to, the antioxidants of the claimed nutrient composition.

Formula 1G includes Formula 1F plus the hormone melatonin (*Id.* at para. [0058]), which is not described as, and is unrelated to, the antioxidants of the claimed nutrient composition.

Formula 1H includes Formula 1G plus Gymnema sylvestre (a plant extract), fenugreek seed (a food stuff), an omega-3-fatty acid, gingko biloba (an herb), and lycopene. *Id.* at para. [0061]. These additions similarly are not described as, and are unrelated to, the antioxidants of the claimed nutrient composition.

The Kosbab formulation pattern exemplified above continues for the remaining Formulations II-V. Briefly, Kosbab begins with base Formulas II, III, IV or V having components appearing to be unrelated to the claimed nutrient composition and then adds constituents which also appear to be unrelated to the claimed composition. Because Kosbab's base Formulas I-V do not contain or suggest a composition with an optimal combination of at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants, and because the remainder of Kosbab's are extrapolations from Kosbab's base formulas I-V which list components not described as, and unrelated to, the claimed antioxidant nutrient composition, Kosbab cannot provide the proper teaching, suggestion or motivation to arrive at a composition containing at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants.

For example, Kosbab lists nutrient, plant extract, food stuff (fenugreek seed, red wine extract), herbal substance (Gingko biloba, Gymnema sylvestre), hormones (melatonin), enzyme (superoxide dismutase, catalase, and glutathione peroxidase), digestive aid (betaine hydrochloride and pepsin), chemical buffer (sodium bicarbonate), shark cartilage, seaweed, non-antioxidant amino acid (taurine), dragons blood [0169], medication (aspirin) and antibiotic [0159]. Therefore, of the wide variety of additions listed by Kosbab, none teach or suggest a modification that would include an optimal combination of at least one vitamin antioxidant, at least one mineral antioxidant and a highly saturable amount of at least three high potency antioxidants. Hence, the Office's conclusion appears to be a hindsight reconstruction focusing

on the solution to the problem after reading Applicant's application and ignoring the requirement for a teaching, suggestion or motivation in the art for establishing a *prima facie* case of obviousness.

In light of the above remarks, Applicants maintain that the Office has failed to establish a *prima facie* case of obviousness because the motivation, teaching or suggestion has been omitted. The Office's analysis appears to have incorrectly applied hindsight from the solution of the inventor's problem rather than to the problem itself. Applicants maintain that they have met their burden and respectfully request withdrawal of this ground of rejection.

Claims 1-27 also stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Gorsek in view of Ames et al., U.S. Patent No. 5,916,912, and Kosbab. Gorsek and Kosbab are cited as described above. Ames et al. is cited allegedly for describing a formula having at least one antioxidant and acetyl L-carnitine for restoring mitochondrial function in older animals. The Office alleges that it would have been obvious to modify the composition of Gorsek with a highly saturable amount of acetyl L-carnitine as suggested by Ames et al. and Kosbab for the purpose of reversing the indicia of aging. Motivation for the combination is alleged to derive from the restoration of youth being a desirable health benefit and marketing feature.

As described previously, the "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *In re Kahn*, Case No. 04-1616, slip op. at p.11 (Fed. Cir. March 22, 2006). The cited combination of Gorsek, Kosbab and Ames et al. fails to render the invention obvious because, at most, these references provide nothing more than the mere identification of elements of the claimed invention. Accordingly, the cited combination fails to provide the required teaching, suggestion or motivation for one of ordinary skill to arrive at the claimed invention containing a saturable amount of at least three high potency antioxidants.

Gorsek and Kosbab fail to teach or suggest a saturable amount of at least three high potency antioxidants as described previously. Also as described previously, Kosbab lacks the requisite motivation to combine components into a composition containing a highly saturable amount of at least three high potency antioxidants. The combination of Ames et al. with Gorsek and Kosbab similarly fail to teach, suggest or motivate one of ordinary skill to arrive at the

claimed invention because Ames et al. is directed to using two antioxidants for enhancing mitochondrial function. As with Kosbab, there is nothing apparent in Ames et al. that would suggest to one of ordinary skill to formulate together at least three high potency antioxidants. Nor is there anything apparent in Ames et al. that would suggest to one of ordinary skill in the art to formulate at least three high potency antioxidants in highly saturable amounts because Ames et al. teaches that two antioxidants achieve the intended purpose. For example, Ames et al. describes:

> We have found that carnitine (a normal mitochondrial metabolite used to transport fatty acids into the mitochondria as fuel) and carnitine derivatives, when put into the drinking water of old animals, restore the cardiolipin and membrane potential of their mitochondria. At the same time, the carnitines increase the flux of reactive oxygen species from the mitochondria. We have found that we can specifically alleviate this enhanced flux with mitochondrially active antioxidants, such as lipoic acid. The two reagents given to old animals, restored **all** three mitochondrial functions and reversed several gross indicia of aging, including activity, muscle tone, coat appearance and kidney morphology.

Ames et al., col. 1, lines 36-47 (emphasis added).

As described by Ames et al. above, the inclusion of both carnitine and lipoic acid in drinking water restores all three mitochondrial functions related to aging cells. Accordingly, Ames et al. fail to teach or suggest at least three high potency antioxidants - a claimed element also missing from both Gorsek and Kosbab. Moreover, because Ames et al. teach that two antioxidants achieve the intended purpose, one of ordinary skill in the art also would not be motivated to include additional antioxidants in any of the formulations of Gorsek, Kosbab or Ames et al. because there is no need to include more antioxidants. Accordingly, the combination of Gorsek, Kosbab and Ames et al. cannot render the invention as claimed obvious and withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

In light of the Amendments and Remarks herein, Applicants submit that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

David A. Gay
Registration No. 39,200

4370 La Jolla Village Drive, Suite 700
San Diego, CA 92122
Phone: 858.535.9001 DAG:dcd
Facsimile: 858.597.1585
Date: September 20, 2006

Please recognize our Customer No. 41552 as our correspondence address.

SDO 49966-1.069738.0011